

REMARKS

In this Amendment, claims 16, 20, and 21 are amended; claims 34-37 are new; and claims 1-15, 17, 19, 22-33 are canceled without prejudice. After entry of this Amendment, claims 16, 18, 20, 21, and 34-37, which are drawn to a kit for diagnosing prostate cancer, will be pending.

The following amendments have been made to the claims.

Independent claim 16 has been amended to recite the limitations of dependent claim 17, which is canceled. Thus, amended claim 16 recites “an antibody.”

Independent claim 16 has also been amended to recite that the antibody is “raised against RM2 antigen.” This amendment is supported by the specification at paragraphs 31 and 32, describing the production of polyclonal and monoclonal antibodies, for example. Specifically, paragraph 31 states, “a mammal (e.g., a mouse, hamster, or rabbit) can be immunized with an immunogenic form of the RM2 antigen.”

In addition, the term “epitope,” and the language “from a specimen obtained from a patient suspected of having prostate cancer,” have been removed from the independent claim because they are believed to be unnecessary. For example, paragraph 7 of the specification states that R may be a “synthetic carrier,” and thus, it is not necessary that the recited immunogenic antigen be isolated from a patient. Further, in view of the fact that R may be a glycoprotein (see paragraph 23), the structure recited in the claims was not intended to define the precise “epitope” of the antibody.

Dependent claims 20 and 21 have been amended to be consistent with independent claim 16.

Claims 34-37 further define the RM2 antigen, as described in the specification at paragraphs 19-23.

No new matter has been introduced.

Entry of this amendment is requested.

I. Response to Claim Rejections Under 35 U.S.C. §112, Second Paragraph

At page 2 of the Office Action, claims 21 and 32 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for the following reasons.

(1) The Examiner states that the language “said RM2 antibody” in claim 21 lacks antecedent basis.

The amendments to claim 21 address this issue.

(2) The Examiner states that the language “said at least one antibody” in claim 32 lacks antecedent basis.

Claim 32 has been canceled.

Withdrawal of these rejections is requested.

II. Response to Claim Rejections Under 35 U.S.C. § 112, First Paragraph

At pages 3-5 of the Office Action, claims 16 and 22-25 are rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement.

Specifically, while the Examiner acknowledges at page 5 of the Office Action that the specification provides a written description of antibodies that bind to the RM2 antigen, the Examiner states that other “moieties” that bind to RM2 antigen are not sufficiently described.

The claims have been amended to recite an “antibody.”

Withdrawal of this rejection is requested.

III. Response to Claim Rejections Under 35 U.S.C. § 103(a)

(1) At page 6-7 of the Office Action, claims 16-27 and 30-31 are rejected under 35 U.S.C. §103(a) as being obvious over Saito et al., *J. Biol. Chem.* 269:5644-5652 (1994), in view of Cordon-Cardo et al. (U.S. Patent 5,168,043).

Specifically, the Examiner states that Saito et al. teach a monoclonal antibody that specifically recognizes a tetrasaccharide epitope present in the recited RM2 antigen.

The Examiner acknowledges that Saito et al. do not teach a kit comprising the RM2 antibody.

However, the Examiner contends that Cordon-Cardo et al. teach diagnostic kits comprising monoclonal antibodies.

The Examiner concludes that it would have been obvious to one of ordinary skill in the art at the time the invention was made to package the antibody taught by Saito et al. in the form of a kit.

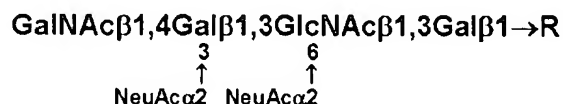
(2) At pages 7-8, claims 28-29 are rejected under 35 U.S.C. §103(a) as being obvious over Saito et al., in view of Cordon-Cardo et al., and further in view of Tannock and Hill, The Basic Science of Oncology, 3rd Ed. (1998).

The Examiner acknowledges that neither Saito et al. nor Cordon-Cardo teaches detection via sodium dodecyl sulfate polyacrylamide gel electrophoresis (SDS-PAGE) followed by Western blot analysis.

However, the Examiner contends that Tannock and Hill teach this analysis.

The Examiner concludes that one of ordinary skill in the art at the time the invention was made would readily have substituted the immunohistochemical means taught by Saito et al. for SDS-PAGE followed by Western Blotting as taught by Tannock and Hill.

Independent claim 16 has been amended to recite “an isolated antibody raised against RM2 antigen, wherein said RM2 antigen comprises the structure shown below, wherein R represents a carrier.



Saito et al. (as well as the other cited references) do not teach the RM2 antigen recited in the present claims, and thus do not teach an antibody raised against the same. Saito et al. teach, in the Abstract, raising antibodies against a different structure (DSGG; see page 5645, left column of Saito et al.).

Further, Saito et al. do not teach raising antibodies against the recited antigen as isolated from a prostate cancer patient, as recited in new claim 37.

The present claims are therefore non-obvious over the cited references.

Withdrawal of these rejections is requested.

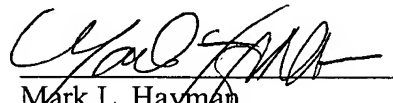
AMENDMENT UNDER 37 C.F.R. § 1.111
Application No. 10/812,357

Attorney Docket A8739

In view of the above, reconsideration and allowance of this application are now believed to be in order. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

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